DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 8 2008

Rec'd Electronically 8/11/08 EST 2/2011

Judy Slome Cohain

[redacted]

Re: Docket No. 2007P-0483

Dear Ms. Cohain:

This letter responds to your citizen petition dated December 2, 2007, requesting that the Food and Drug Administration (FDA) "restore FDA approval to Tecsana Epi-No birth trainer and remove adverse event report on Tecsana Epi-No from [the FDA] website."

Your request that FDA "restore" approval to the Tecsana Epi-No Birth Trainer is based in a misunderstanding of the status of the device. A search of FDA's official records does not reveal any valid premarket approval or clearance, or any exemption from applicable requirements of the Federal Food, Drug, and Cosmetic Act (the Act), as amended, for a device known as a Tecsana Epi-No birth trainer, which you describe as a pelvic floor muscle exerciser intended for use in birth preparation. The statement in your petition, "FDA approval was cancelled after an adverse event report in which someone used the Epi-No in an unapproved fashion" is an incorrect statement. Thus FDA is denying this request.

Your request that FDA remove the adverse event report from the agency website is also denied. MedWatch, FDA's safety information and adverse event reporting program, allows healthcare professionals and consumers to report adverse events that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use (see http://www.fda.gov/medwatch/what.htm). The Center for Devices and Radiological Health (CDRH) enters adverse event reports involving devices in its searchable online Manufacturer and User Facility Device Experience Database (MAUDE) (see http://www.fda.gov/cdrh/maude.html). As described on FDA's website, this database is intended to include all reports received at the time of an update, but is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. Therefore, FDA does not remove adverse event reports from the MAUDE database or the agency's website once they have been posted.

If you have any questions, please contact Paul Gadiock of the CDRH Regulations Staff at (240) 276-2343.

Sincerely yours,

Jeffrey Shuren
Associate Commissioner for
Policy and Planning

FDA-2007-P-0184

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